Notice of Allowability	Application No.	Applicant(s)	
	10/808,397	LEVIN ET AL.	
	Examiner	Art Unit	
	MATTHEW F. DESANTO	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *02/22/2010*.

2. ☒ The allowed claim(s) is/are *1-14, 20-47*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *06/07/2010* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jeffry Nelson on June 7, 2010.

The application has been amended as follows:

AMENDMENTS TO THE SPECIFICATON:

Please substitute the following amendment paragraph for paragraph 0040 of the original specification:

[0040] In one embodiment, ~~An object of~~ the invention ~~is to reduce~~reduces the severity and complications of MI by reducing the infarct expansion~~. It is the objective of this invention to achieve this goal by~~ which may be achieved by reducing stress in the infarcted ventricle by constraining the heart and reducing the diastolic dilation of the heart. ~~It is the objective of this invention to reduce the~~ The infarct expansion may be reduced with a procedure that is practical, simple, easily reversible, and minimally invasive (does not require general anesthesia and surgery).

AMENDMENTS TO THE Claims:

Claim 1:

A method for treating a heart in a human patient having a pericardial sac comprising:

a. inserting only a distal tip of a catheter into the pericardial sac of the patient;

b. infusing fluid through the catheter into the pericardial sac and increasing a fluid pressure in the pericardial sac;

c. constraining the heart with the infused fluid and the resulting increased fluid pressure to form at least a partial cardiac tamponade, and

d. reducing dilation of the heart by the constraint on the heart.

Claim 11:

A method to constrain a heart of a mammalian patient, wherein the heart is in a pericardial sac, said method comprising:

a. inserting only a distal section of a catheter into the pericardial sac, wherein the distal section does not surround the heart;

b. infusing a fluid from the distal section and into the pericardial sac to form at least a partial cardiac tamponade;

c. increasing a fluid pressure in the pericardial sac by the infusion of the fluid, and

d. reducing a dilation of the heart by the cardiac tamponade ~~fluid pressure increase~~ in the pericardial sac.

Cancel claims 15-19

Claim 20:

A method for treating the heart comprising:

infusing a flowable material into the pericardial sac of the heart, wherein the flowable material flows through a distal tip of a catheter inserted into the pericardial sac and the flowable material contacts tile pericardial sac, wherein only the distal tip of the catheter extends into the pericardial sac,

continuing the infusing at least until the flowable material in the pericardial sac is a sufficient volume to increase a pressure in the sac to form at least a partial cardiac tamponade, and thereby constrain the heart and reduce diastolic dilation of the heart, and

reduce dilation of the heart by the constraint on tile heart resulting from the cardiac tamponade ~~infused flowable material~~.

Claim 27:

A method for treating a heart of a mammalian patient, the method comprising:

infusing a flowable material into a pericardial sac of the heart, wherein the flowable material is inside and in contact with tile pericardial sac, wherein the flowable material is infused from a distal section of a catheter, only the distal section of the catheter extends into the pericardial sac, and the distal section does not surround the heart;

forming a hydraulic shell around at least a portion of the heart by the infusion of the flowable material into the pericardial sac, wherein the hydraulic shell increases a

pressure in the pericardial sac due to the infusion of the flowable material and forms at least a partial cardiac tamponade, and

constraining the heart with the cardiac tamponade ~~hydraulic shell~~ and thereby reducing dilation of the

heart.

Claim 36:

A method for treating a mammalian patient having a dilated heart enclosed inside a pericardial sac comprising:

a. inserting a distal tip of a catheter into the pericardial sac of the patient, wherein only the distal tip of the catheter enters the pericardial sac;

b. infusing fluid through the catheter into the pericardial sac, wherein an amount of fluid is infused to substantially increase a fluid pressure in the sac and forms at least a partial cardiac tamponade;

c. constraining the heart with the cardiac tamponade ~~infusion in the pericardial sac~~ to substantially reduce the dilation of the heart, and

d. sealing a puncture in the pericardial sac formed to infuse the fluid.

Claim 37:

A method for treating a dilated heart in a pericardial sac of a mammalian patient, the method comprising:

a. inserting only a distal section of a catheter in the pericardial sac, wherein the distal section does not surround the heart;

b. infusing fluid through the catheter into the pericardial sac, wherein an amount of fluid is infused to substantially increase a fluid pressure in the sac and form at least a partial cardiac tamponade;

c. constraining the heart with the cardiac tamponade ~~infusion in the pericardial sac~~ to substantially reduce the dilation of the heart, and

d. sealing the pericardial sac.

Claim 38:

A method for reducing expansion of an infarct of a heart in a human patient having a dilated heart enclosed inside a pericardial sac comprising:

a. inserting only a distal section of a catheter in the pericardial sac of a patient, wherein the distal section does not surround the heart;

b. infusing the fluid through the catheter into the pericardial sac;

c. infusing sufficient fluid to cover substantially the entire surface of the heart with the fluid and to substantially increase a pressure in the pericardial sac, and

d. constraining the heart with the fluid substantially covering the heart to substantially reduce the dilation of the heart, wherein the fluid forms at least a partial cardiac tamponade.

Claim 40:

A method for treating a patient with dilated heart comprising:

inserting into a pericardial sac surrounding the heart only a distal section of a catheter, wherein the distal section does not surround the heart;

creating a cardiac tamponade of the heart by controlled infusion of a fluid from the distal section of the catheter into the pericardial sac to increase a fluid pressure in the pericardial sac, wherein the fluid is in contact with the pericardial sac;

constricting the heart by the infusion which forms at least a partial cardiac tamponade, and

dilating the heart by the constriction of the heart due to the cardiac tamponade.

Claim 41:

A method for treating a patient with dilated heart comprising:

inserting into a pericardial sac surrounding the heart only a distal section of a catheter and the distal section does not surround the heart;

creating a hydraulic shell around the heart by controlled infusion of a fluid from the distal section of the catheter into the pericardial sac, wherein the fluid is in contact with the pericardial sac and the hydraulic shell increases a fluid pressure in the pericardial sac;

constricting the heart by the infusion which forms at least a partial cardiac tamponade, and

dilating the heart by the constriction of the heart due to the cardiac tamponade.

Claim 42:

A method for treating a heart in a mammalian patient comprising:

extending a catheter through a blood vessel adjacent a pericardial sac of the heart;

puncturing a wall of the blood vessel and the pericardial sac with a distal section of the catheter, wherein only the distal section extends into the pericardial sac and the distal section does not surround the heart;

infusing a flowable material from the distal end of the catheter to the pericardial sac of the heart;

forming a hydraulic shell around at least a portion of the heart, by the infusion of the flowable material into the pericardial sac, wherein the hydraulic shell increases a fluid pressure in the pericardial sac and thereby forms at least a partial cardiac tamponade, and

constraining the heart with the cardiac tamponade formed by the hydraulic shell.

Claim 45:

A method for treating a mammalian patient having a dilated heart enclosed inside a pericardial sac comprising:

inserting only a distal section of a catheter into the pericardial sac of the patient, wherein the distal section does not surround the heart;

infusing fluid through the catheter into the pericardial sac to increase a fluid pressure in the pericardial sac and form at least a partial cardiac tamponade, and

constraining the heart with the cardiac tamponade ~~increased fluid pressure in the pericardial sac~~ to substantially reduce the dilation of the heart.

Claim 46:

A method for reducing abnormal dilation of a heart to treat at least one of acute myocardial infarction and heart failure conditions, the method comprising:

positioning a fluid infusion device such that at least one opening at a distal section ~~end~~ is inside the pericardial sac and a proximal end of the device is outside of the patient, wherein only the distal section extends into the sac and the distal section does not surround the heart,

pumping fluid through the device to infuse the fluid into the pericardial sac to increase a pressure in the pericardial sac and form at least a partial cardiac tamponade,

constraining the heart with the cardiac tamponade ~~infusion~~ and,

sealing the pressurized fluid within the pericardial sac~~,~~.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-14, 20-47 are drawn to a method of infusing a fluid into the pericardial sac, classified in class 604, subclass 500.

   II. Claims 15-19 are drawn to a infusion system, classified in class 604, subclass 131.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a totally different process such as a teaching model.

4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Jeffry Nelson on June 7, 2010 a provisional election was made without traverse to prosecute the invention of Group I. Affirmation of

this election must be made by applicant in replying to this Office action. Claims 15-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found were method claims that dealt with inserting a short portion of a catheter into pericardial sac and infusing fluid into the pericardial space through the catheter so that pressure would increase and constrain the heart (cardiac tamponade).

The independent claims also include other patentable subject matter in combination with the other elements or steps of the claim not mention in the above paragraph.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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